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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,835	08/25/2000	Scott Koenig	469201-493	4179

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Alan J Grant
Carella Byrne Bain Gilfillan Cecchi Stewart &
Olstein
6 Becker Farm Road
Roseland, NJ 07068

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/645,835	KEONING ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-30 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) 9-24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-38 is/are allowed.
- 6) ☒ Claim(s) 25-30 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>11/6/03</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 9-30 and 33-38 are pending.

Applicants' amendment filed on August 11, 2003 is acknowledged, and applicants' response has been fully considered. Claims 9-24 are non-elected inventions and remain withdrawn from consideration. Claims 33-37 have been amended, and a new claim 38 has been added, thus claims 25-30 and 33-38 are examined.

Objection Withdrawn

2. The previous objection of claim 36, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 6-7 in the amendment filed August 11, 2003.

Rejection Withdrawn

Claim Rejections - 35 USC § 102

3. The previous rejection of claims 33-35 under 35 U.S.C. 102(e) as being anticipated by Brodeur *et al.* (US 2003/0031682) is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 6 in the amendment filed August 11, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25-30 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 25-30 and 33-35 are directed to a polypeptide comprising an amino acid sequence having at least 75%, 90%, or 95% sequence identity to SEQ ID NO:4, wherein the polypeptide binds to an antibody specific for Sp36 (claims 25-27); to a polypeptide comprising an amino acid sequence having at least 75% sequence identity to SEQ ID NO:2 or 4, wherein the polypeptide is present in an organism of Group A streptococci (GAS) or *Straphylococcus aureus* and the polypeptide binds to an antibody specific for Sp36 (claims 28-30); or to a polypeptide comprising an amino acid sequence having at least 75%, 90%, or 95% sequence identity to SEQ ID NO:4, wherein the polypeptide has a sequence with at least 25% sequence identity to Sp36 (SEQ ID NO:7) (claims 33-35). The specification indicates that the polypeptides which have at least 75%, 90% or 95% sequence identity to SEQ ID NO:2 or 4 (page 11, lines 12-16) can be used as a vaccine (page 22, lines 7-10), and that antiserum raised against the pneumococcal Sp36 protein cross-react with Sp36 homolog identified from the group B streptococci (GBS), which indicating conservation of epitopes between the polypeptides, and because the group A and B homologs are highly homologous, thus antiserum would also likely cross-react with the group A streptococcal protein (Example 4). However, the specification also indicates GBS (SEQ ID NO:6) has 25.6% sequence homology to Sp36 (SEQ ID NO:7), 97.7% homology to GAS 36 (SEQ ID NO:2), and 11.6% homology to GAS36(2) (SEQ ID NO:4); and GAS36(2) (SEQ ID NO:4) has 12.6% sequence homology to Sp36 (Table 1). Since GAS36(2) (SEQ ID NO:4) has low sequence homology against GBS (SEQ ID NO:6) or Sp36, and the specification does not specify which portion of the polypeptide is identical to SEQ ID NO:4 or 2 and binds to an

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antibody specific for Sp36, nor indicates which portion of the polypeptide is identical to SEQ ID NO:4 and SEQ ID NO:7, thus it is not known which region of the polypeptide is essential for the activity. Furthermore, there is no disclosure identifying the sequences having at least 75%, 90%, or 95% sequence identity to SEQ ID NO:2 or 4 that bind to an antibody specific for Sp36.

Without guidance for structure to function/activity, one skilled in the art would not know which region or residue of SEQ ID NO:2 or 4 is essential for function/activity and how to identify a functional polypeptide. The lack of a structure to function/activity relationship and the lack of representative species for the polypeptides having at least 75%, 90%, or 95% sequence identity to SEQ ID NO:2 or 4 that bind to an antibody specific for Sp36 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

In response, applicants indicate Example 4 of the application describes reaction between group B protein and the indicated antibody to Sp36 as well as how this was measured, in addition, it is well known in the art how to generate polypeptides with amino acid substitutions, deletions, additions and how to measure cross-reactivity of a claimed polypeptide with an anti-Sp36 antibody; Example 14 of the guidelines for the written description requirement indicate the sample claim therein was to a protein comprising the recited sequence or 95% identical thereto and which catalyzes reaction of A to form product B, and the conclusion was that a rejection for failure to meet the written description requirement was not proper because the art of amino acid sequence substitution was well known in the art and an assay for the enzyme activity was disclosed, more particularly, the guidelines note that the recited sequence was novel and

unobvious, the specific sequence was the only species actually disclosed, and the genus is sufficiently narrowed because all variants must exhibit the recited enzyme activity; and the present application provides a specific sequence is both novel and unobvious, e.g., claim 25 recites a peptide with at least 75% identity to the recited sequence and recites a specific antibody (anti-Sp36) for use in testing members of the claimed genus for their ability cross-react with the antibody, and Fig. 2 in Example 5 shows sequence alignments of the disclosed homologs with Sp36 (pages 4-6 of the response in Paper No. 18 filed March 28, 2003). The response has been fully considered, however, the argument is not found persuasive because the specification only shows the reaction between the homolog from GBS (e.g., SEQ ID NO:6) and the antibody specific to Sp36 (Example 4), it does not identify the epitope sequence in the polypeptide, nor demonstrates the homologs from GAS such as analogs of SEQ ID NO:4 (at least 75% homology to SEQ ID NO:4) cross-react with antibody to Sp36, considering GAS36(2) (SEQ ID NO:4) has very low sequence homology (11.6% and 12.6%) to GBS (SEQ ID NO:6) or Sp36. Furthermore, Fig. 2 of Example 5 only provides the sequence alignments of GAS36 (SEQ ID NO:2), GBS 36 (SEQ ID NO:6) and Sp36 (SEQ ID NO:7), it does not include GAS36(2) (SEQ ID NO:4), and the homologous regions between the polypeptides are not identified. Regarding the guidelines for the written description requirement, Example 14 indicates the genus does not have substantial variation because all variants must have at least 95% sequence identity to the recited sequence and must exhibit the recited enzyme activity, while in the instant application, the claimed polypeptides have substantial variations because the variants have only 75% sequence identity to SEQ ID NO:4 or 2 with binding activity to antibody specific to Sp36, where the homologous regions between the polypeptides (e.g., GAS36, GAS36(2) and Sp36) are not defined.

Conclusion

5. Claims 25-30 and 33-35 are rejected. It appears claims 36-38 are free of art of record.

A telephone call was made to Applicant by the Examiner on November 6, 2003 (See attached Interview Summary) indicating claims 36-38 are allowable, but there is written description issue regarding claims 25-30 and 33-35, Applicant indicates he does not want to make decision regarding those claims and would like to see the Office Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

November 6, 2003

Christopher S. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600